## GENERAL INFORMATION AND GUIDELINES

- For all studies, storage food, blood and urine are not to be destroyed until the Final Report is released. MDS will still need written approval, per study. MDS will use left over urine for validation.
- Sample shipments to 3rd party vendors (short term studies) usually within 2-3 days after completion of clinical conduct.
- General timeline for analysis of samples/QC review/QA review to close of clinic is approximately 6 weeks. This assumes that the assay is scheduled to start upon receipt of samples.
- MDS issues an analytical report for each analyte assayed. MDS will also reference these reports in the Final Reports.
- As a general rule, MDS Clinical Database Lock usually occurs 2 weeks after conduct completes, Analytical Database Lock completes 2-3 months after conduct completes, Statistical Database Lock usually occurs two weeks after Analytical Database Lock is complete. Draft Report usually provided 6-8 weeks after Statistical Lock.
- PM would like Table of Contents for all report volumes in one area (Master TOC). With all hardcopies, a hard cover 3 ring binder or spiral binder is needed for each volume. MDS will number volumes (Vol. 1 of 32, Vol. 2 of 32, etc.).
- As a standard, Volume 1 (e-mailed), 10 CDs (mailed via overnight), and one complete hard copy (mailed via ground) of both the Draft Report and Draft Final Report will be sent to Valerie. For the Final Report, one hard copy and 5 CDs will be sent to Valerie.
- Standard report review and preparation process: MDS will send Draft Report to Valerie; PM will review and provide MDS with a track-changed document. A mini-teleconference will be held between MDS and PM Team to discuss any questions or feed-back. MDS will then revise Draft Report and send a Draft Final Report to PM. If no further changes, PM will provide approval for MDS to release the Final Report.
- Standard report review and preparation timelines: PM Review of Draft Report: 4 weeks; MDS Draft Final Report Prep: 4 weeks; PM Draft Final Report Review: 2 weeks; MDS Final Report Prep: 1 week
- Repository protocols will be prepared for current and future studies.
- Letters of Administrative Change will be provided to the IRB as information only. IRB approval is only sought for formal amendments to the study protocol.
- MDS to send topography units to Plowshares for cleaning/recalibration after each 10-day study, prior to start of long term component.
- Data Management Plans are not needed for each protocol. The standard plan will be used for each study, with additional (specific) details to be covered in the individual protocols.
- For all SAEs, MDS to complete Med Watch Form and submit to IRB.
- IRB correspondence should go to primary contact for individual studies, PM Study Manager.

### Next Meeting:

Wednesday, 28 January 2004

10:00 CST, 11:00 EST

Here is the NEW call-in number to be used:

**US Number: 866-365-4406**

**International Number: 303-248-9655**

**Code: 4374773**



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